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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,318	07/01/2003	Sylvia G. Kachalsky	2094/0878/67656-A/JPW/FHB	4833

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EXAMINER	
CHERNYSHEV, OLGA N	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,318	KACHALSKY ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *10 and 13-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 July 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/30/4*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on June 05, 2006 is acknowledged. The traversal is on the ground(s) that Groups I and II encompass polynucleotides, which encode STR50, and therefore represent splice variants of the same gene. This is found persuasive and Groups I and II have been rejoined.

Claims 10 and 13-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 05, 2006.

Claims 1-9 and 11-12 are under examination in the instant office action.

Drawings

2. The figures 1-3 of the instant application are presented on separate pages or in separate panels. 37 C.F.R. § 1.84(u) (1) states that in cases when figures present partial views of a drawing, which are intended to form one complete view, whether contained on one or several sheets, the figures must be identified by the same number followed by a capital letter. For example, the three pages of Figure 1 in the instant specification should be renumbered "Figure 1A" – "Figure 1C" rather than "Figure 1". Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84(u) (1), the specification should be amended to change the Brief Description of the Drawings and the rest of the

specification to refer to each Figure accordingly. If, for example, Figure 1 is divided into Figures 1A-1C, then the Brief Description and all the references to this figure in the specification must refer to this Figure in the same manner.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 11-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims fail to include any limitations, which would distinguish the claimed polynucleotides from those which occur in nature. In the absence of the hand of man, naturally occurring nucleic acid molecules and proteins are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Filing of evidence of a new utility imparted by the increased purity of the claimed invention and amendment of the claims to recite a purity limitation, if supported by the specification, is suggested to obviate this rejection. Applicant should point to the basis in the specification for any amendment to the claims.

5. Claims 1-9 and 11-12 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well-established utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

It is clear from the instant application that the protein described therein is what is termed an "orphan protein" in the art. The DNA of the instant application has been isolated because of its similarity to a known DNA. There is little doubt that, after complete characterization, this DNA and encoded protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion".

The instant claims are drawn to an isolated nucleic acid molecules encoding a polypeptide of as yet undetermined function or biological significance. It is clear from the instant specification that the claimed novel nucleic acid molecules of SEQ ID NO: 1 and SEQ ID NO: 3 encode a polypeptide designated STR50 (also known as MEG-3 polypeptide, p. 6), which is asserted to be "modulated as a result of neurotoxic stress" (p. 5 of the instant specification).

More specifically, "the inventors suggest that STR50 is involved in the apoptosis of cells which accompanies neurotoxic events; it would therefore be beneficial to inhibit STR50 in diseases where such apoptosis is detrimental, and enhance STR50 in diseases where such apoptosis is beneficial" (bottom at page 8). It is further stated in the instant specification that the instant STR50 molecules can be used to treat different pathological conditions ("adverse consequences of central nervous system injuries that result from any of a variety of conditions", p.16), which include neurodegenerative diseases, ischemia, cardiac arrest, spinal cord trauma and metastatic or primary tumors (pp.15-17). Finally, working examples presented in the instant specification are limited to disclosure of (1) isolation and purification of STR50 (pp.31-34); (2) pattern of up-regulation of expression of STR50 during experimental shock/ischemic conditions (pp.35-36); and (3) prophetic protocols explaining how to use STR50 gene or polypeptide in screening assays and pharmaceutical formulations (pp.45-55).

In the absence of knowledge of the biological significance of this specific nucleic acid and encoded protein, there is no immediately obvious patentable use for the polynucleotide or the encoded protein. The instant specification fails to provide any factual evidence or sound scientific reasoning that would support a conclusion that the instant nucleic acid or encoded protein is associated with any diseases or disorder, including pathological conditions specifically recited on pages 15-17 of the disclosure. To employ the DNA and the protein in the future methods of treatment diseases or diagnostic assays is not a "real world" because it would eventually relate to a protein for which no biological function is known. The instant application also fails to demonstrate use of the claimed STR50 polynucleotides as a marker for any disease or condition (which would be a real world use). Because the instant specification does not teach

a biological activity of the protein, which supports a practical utility, one would not reasonably believe that the administration of the STR50 encoded by the claimed nucleic acid molecules would prevent or treat a condition or disease, like for treating a neurodegenerative disease, stroke or cancer, as implied by the specification. To employ a nucleic acid of the instant invention in any of the disclosed methods would clearly be using it as the object of further research, which has been determined by the courts to be a utility, which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the encoded protein in their currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-9 and 11-12 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7. Claims 2-5 and 11-12 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2-5 are directed to nucleic acids that are homologs of polynucleotides of SEQ ID NO: 1 and 3 or fragments 644 to 3109 of SEQ ID NO: 1 and SEQ ID NO: 3. Claims 11-12 encompass fragments of 10 to 766 or to 922 consecutive nucleotides within sequence of SEQ ID NO: 1 and SEQ ID NO: 3, respectively. The claims do not require that the polynucleotides or their fragments possess any particular conserved structure or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polynucleotides that is defined only by structural similarity. However, the instant specification fails to describe the entire genus of nucleic acid molecules, which are encompassed by these claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of nucleic acid molecules which encode proteins which have the amino acid sequence of SEQ ID NO: 2 and 4. These nucleic acid molecules have nucleic acid sequence of SEQ ID NO: 1 and SEQ ID NO: 3, respectively. The claims are drawn to nucleic acid molecules that are homologs and fragments of these disclosed polynucleotides of SEQ ID NO: 1 and SEQ ID NO: 3. Thus, the claims are not limited to a nucleic acid with a specific sequence. The claims only require the claimed polynucleotides to share some degree of structural similarity to the polynucleotides of SEQ ID NO: 1 and SEQ ID NO: 3. The specification only describes a polynucleotide of SEQ ID NO: 1 and a polynucleotide of SEQ ID NO: 3 and fails to teach or describe any other nucleic acid sequence which lacks the sequence of SEQ ID NO: 1 or SEQ ID NO: 3 and has any relevance to STR50 protein.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of "homology" or length of a fragment. There is not even identification of any particular portion of the structure that must be conserved. As stated above, it is not even clear what region of the encoded polypeptide has the disclosed activity. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of homologs and fragments, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only polynucleotides comprising the nucleic acid sequence set forth in SEQ ID NO: 1 and in SEQ ID NO: 3, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1 and 8-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 1 is vague and indefinite in so far as it employs the term "STR50" as a limitation. This term is appears to be novel, and without a reference to a precise amino acid sequence identified by a proper SEQ ID NO: one cannot determine the metes and bounds of "STR50". Moreover, because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a "STR50", an artisan cannot determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.

11. Claims 8-9 are indefinite for being dependent from indefinite claim.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 11 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Young et al., US Patent 6,525,174, 2003, filing date of 12/04/1998.

Claims 11 and 12 encompass fragments of polynucleotides of SEQ ID NO: 1 and SEQ ID NO: 3 as short as 10 consecutive nucleotides. Patent of Young et al. discloses nucleotide sequences that have at least 29.6% sequence similarity, with 98.2% local similarity to the instant SEQ ID NO: 3, see copy of the sequence alignment attached to the instant office action (polynucleotide of SEQ ID NO: 3 is substantially similar to the SEQ ID NO: 1, by Applicant's own admission, see Applicant's response to the Restriction requirement filed on June 05, 2006). Thus, Young et al. fully anticipate the instant claimed invention of claims 11 and 12.

Conclusion

14. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

July 11, 2006